REMARKS

The Office Action mailed February 27, 2004, has been carefully reviewed and by this Amendment, claim 11 has been canceled, claims 1-3 and 6-10 have been amended, and claims 12-21 have been added. Accordingly, claims 1-10 and 12-21 are pending in the application. Claims 1 and 12 are independent.

The Examiner rejected claim 11 under 35 U.S.C. 112, second paragraph, as being indefinite. Claim 11 has been canceled.

The Examiner rejected claims 1-10 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,643,194 to Negre et al. ("Negre") in view of U.S. Patent No. 5,637,083 to Bertrand et al. ("Bertrand").

The present invention is directed to a subcutaneous valve for the treatment of hydrocephalus. While the valve may be adjusted externally through the use of magnets, one of the problems being solved by the valve of the present invention is that of unintended changes in the valve adjustment upon exposure to a powerful ambient magnetic field, such as might occur in nuclear magnetic resonance procedures. Another problem being solved is that of impaired flow of the cerebrospinal fluid (CSF) inside the valve chamber, which can lead to clogging thereof.

Both of these problems are solved through the inventive structure and function demonstrated by the present invention.

As set forth in claim 1, which has been amended to clarify informalities noted therein, the valve according to the present invention includes a valve body having an internal chamber with a cylindrical side wall, and inlet and outlet ducts for cerebrospinal fluid; both ducts open out in the side wall of the chamber. A valve member or ball is mounted on a seat at the inside end of the inlet duct, and a curved spring blade fits closely against the chamber side wall, urging the ball against its seat. A magnetic moving member, which is movable under control from outside the valve, is used to adjust the valve pressure and includes a *resilient flexible arcuate blade* that fits closely to the *cylindrical* inside wall of the chamber over at least a fraction of the circumference thereof, while exerting pressure thereon. When subjected to external magnetic force, the moving member with arcuate blade moves in rotation about an axis, with the length of the active portion of the spring blade acting on the valve member, and hence the pressure exerted thereby, being determined by the position of the moving member. The moving member is immobilized in a desired position by locking elements to ensure that the ball is urged against its seat at the desired pressure even when the valve is subjected to a strong

ambient magnetic field. Furthermore, the shape of the arcuate blade is such that the flow of fluid through the chamber into the outlet duct is not impeded. This structure is not shown by the prior art.

Negre discloses a subcutaneous valve having an inner chamber in which a magnetic rotor is mounted. The rotor is fixed to one end of a leaf spring which acts on the valve member or ball to urge it against its seat. As can be seen in Figures 4 and 5, the rotor is an H-shaped bar which extends diametrically across the interior of the cylindrical valve chamber 5. The lateral branches of this bar serve as guide means for moving parts 10, 11. Each moving part houses a respective micromagnet 12', 13' and is provided with a respective lug 10'a, 11'a that projects radially. The lugs are accommodated within a succession of cavities 4' provided in the internal periphery of the lateral wall 3a of the chamber 5, with the cooperation between the lugs and the cavities acting as locking means to secure the position of the bar inside the chamber.

There is nothing in Negre that teaches or suggests a moving member having a *flexible arcuate blade* which fits closely to the *cylindrical* inside wall of the chamber over at least a part thereof. To the contrary, the bar constituting the moving member in Negre presents two projections from a centrally located

rotor that contact non-cylindrical portions of the chamber wall. The interface between these two diametrically opposed points of contact and the projections is not at all comparable to the extended, generally parallel relationship between the *arcuate blade* and *cylindrical* wall as claimed by the present invention. Whatismore, the effect of improving the immobilization of the moving member, which in the present invention is *due to the specific arcuate shape and resilient nature of the blade*, cannot be achieved with the diametral bar of Negre, nor is such an effect suggested thereby.

Furthermore, the diametral bar of Negre is not shaped to avoid impeding fluid flow but rather constitutes a barrier that impedes the free flow of CSF across the valve chamber. In addition, the use of moving parts which slide between the lateral branches of the H-shaped rotor, creates small "dead spaces" inside the rotor in which the CSF may be trapped. As a result, the structure of Negre is susceptible to bacterial colonization and contamination, one of the specific problems which is solved by the present invention.

Bertrand describes a subcutaneously implantable fluid flow control device having a chamber 40, an inlet 22, an outlet 24 and a valve apparatus in which a ball 94 is urged against a valve seat 92 by a pressure spring 96, an end of which is

supported by a rotor assembly 100. The rotor assembly is comprised of a dual concentric stair step array 102 which cooperates with a base 122, one face of which is provided with legs 134, 136. A magnet is embedded between the base 122 and a cap 124. Finally, a compression spring 132 bearing against the cap 124 at one end and against the valve housing at the other end urges the base 122 in contact with the stair step array 102. This device is completely unlike that of the present invention for several reasons.

First, in Bertrand, the ball 94 and the spring 96 are disposed *outside* of the chamber 40, i.e., in the outlet duct extending between the passageway 70 and the outlet connector 24. As can be seen in Figure 3, the valve seat 92 is provided on the face of the *insert* 88 which is opposite to the face which is in contact with the fluid present in the chamber 40. Consequently, the whole device presents significantly greater dimensions than that of the present invention in which the ball and its actuating device are contained *within* the chamber, with the valve seat being provided at the opening to the inlet duct.

Second, in Bertrand the ball 94 is urged against its seat by a coil spring 96 exerting pressure by compression movement along its longitudinal axis which merges with the longitudinal axis of the valve seat. The rotation of the rotor

assembly 100 adjusts the vertical position thereof by changing the positions of the legs 134, 136 on the steps 108, 110 of the array 102 and, thus, the pressure exerted by the top of the rotor assembly on the spring 96. In short, the rotation of the rotor 100 is converted into a translating movement, causing the coil spring 96 to press with greater or lesser pressure against the ball 94.

In the present invention, by contrast, the amount of pressure exerted on the ball is linked to the distance between the contact point of the ball on the spring blade and the point where the spring blade is fixed in a cantilevered position to the end of the arcuate blade (or, alternatively, to the degree of overlap by the arcuate blade). To say that this is equivalent to the structure of Bertrand is to improperly define all structures according to the result obtained, with no consideration of the means used.

Even considering the spring blade of Negre, there is nothing to suggest the combination of Bertrand with Negre in the manner proposed by the Examiner. The Applicant cannot see how a person of ordinary skill in the art would be induced to combine Negre, in which the ball is *in* the chamber and urged by the *spring blade* against a valve seat provided at the end of the *inlet* duct, with Bertrand in which the ball is *outside* the

chamber and urged by a *coil spring* against a valve seat provided inside the *outlet* duct. There is nothing in these references to suggest this combination and, were the magnetic moving member of Negre to be replaced by the rotor assembly of Bertrand, the resulting device would not even work due to the fact that the coil spring of Bertrand needs to be pressed axially while the spring blade of Negre needs to be moved rotatively. Further, the moving member of Bertrand would completely obstruct the chamber, which negates one of the objects of the present invention, namely to *improve* the flow of CSF.

Finally, the Examiner stated that because Bertrand discloses the basic concept of using two springs to control the bias of the ball in the valve, it would have been obvious "to make the outer wall of the ball-engaging portion of the valve a compression spring in order to more accurately control the bias of the ball in the valve". To the best of Applicant's understanding, the Examiner is proposing that Negre be modified to either replace the leaf spring 16 or the valve seat 15 with a compression spring. Neither of these proposals would result in an arcuate blade which fits closely to the cylindrical side wall of the chamber as claimed by the present invention.

More specifically, to modify Negre by replacing the leaf spring 16 with a compression spring is not reasonable as

this would require a complete redesign of Negre in view of the rotary movement of the spring blade taught therein. As currently designed, a compression spring added to Negre would be moved out of position as the bar (and the attached compression spring) is rotated, and there is nothing in Negre or Bertrand to suggest how such a modification would be effectively implemented. Conversely, there is no justification or incentive for adding an unnecessary compression spring to the valve seat 15 as Negre operates effectively as disclosed and such an addition could only represent a complication, at best.

In summary, Bertrand's use of two coil springs does not in any way suggest the relationship between the spring blade and the arcuate blade of the present invention and the Applicant can see no reasonable way by which Negre may be modified, in view of Bertrand, to obtain the present invention. Accordingly, and in view of the foregoing, Applicant respectfully requests that the full import of the specific and cooperative relationship of the elements of claim 1 be reconsidered and the rejection of such claim withdrawn.

Claims 2-10 are in condition for allowance as claims properly dependent on an allowable base claim and for the subject matter contained therein. Particularly with reference to claim 2, the prior art does not disclose the arcuate blade and, hence,

cannot disclose or suggest the embodiment in which one end of the arcuate blade slides over the inside face of the spring blade to exert pressure thereon. Nor does the prior art disclose fixing of the spring blade to the cylindrical wall of the chamber.

Similarly, the prior art does not teach the fixing of one end of the spring blade to one end of the arcuate blade while the remaining end of the spring blade remains free, as set forth in claim 3. The cooperative relationship of these two blades is simply not shown or suggested in the prior art.

Nor, with respect to claim 4, does the prior art disclose an arcuate blade which, while fitting closely to the cylindrical inside wall of the chamber, has an opening therein for allowing the fluid inside the chamber to pass towards the outlet duct so as to ensure that fluid flow is not impeded. The relationship between the micromagnets and the *arcuate blade* as set forth in claims 7 and 8 is also not shown in the prior art.

Finally, with respect to claims 9 and 10, in the magnetic device for adjusting the valves as described in the Negre and Bertrand patents, the axis of polarity of the magnets is in the plane of the valve chamber, whereas in the present invention the axis of polarity of both magnets is perpendicular to the plane of the valve chamber. Consequently, claims 9 and 10 are distinguishable over the prior art.

New claims 12-21 are in condition for allowance for at the same reasons as claims 1-10.

In view of the foregoing amendments and remarks, allowance of all of the pending claims is respectfully requested.

Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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